

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
NORTHWESTERN DIVISION**

ANGELA K. THOMPSON,)	
)	
Plaintiff,)	Case No. 4:15-cv-00128-CSM
)	
vs.)	TEVA WOMEN’S HEALTH, INC.’S
)	ANSWER AND DEFENSES TO
TEVA PHARMACEUTICALS USA,)	PLAINTIFF’S COMPLAINT
INC., TEVA WOMEN’S HEALTH,)	
INC., TRINITY HEALTH, DAVID)	
AMSBURY, D.O.,)	
)	
Defendants.)	
)	

Teva Women’s Health, Inc. (“Defendant”) responds to plaintiff’s Complaint as follows:

1. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of plaintiff’s Complaint.
2. Defendant admits the allegations in Paragraph 2 of plaintiff’s Complaint.
3. Defendant admits only that it is incorporated under the laws of Delaware. Defendant denies the remaining allegations in Paragraph 3 of plaintiff’s Complaint.
4. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of plaintiff’s Complaint.
5. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 of plaintiff’s Complaint.
6. Defendant admits only that it has manufactured and sold and that Teva Pharmaceuticals USA, Inc. has sold ParaGard® Intrauterine Copper Contraceptives. Defendant denies the remaining allegations in Paragraph 6 of plaintiff’s Complaint.

7. Defendant denies the allegations in Paragraph 7 of plaintiff's Complaint.

8. Defendant denies the allegations in Paragraph 8 of plaintiff's Complaint.

9. Defendant admits only that risks of intrauterine pregnancy, ectopic pregnancy, pelvic infection, embedment, migration, perforation of the uterus, expulsion, Wilson disease, vaginal bleeding, septic abortion, dysmenorrhea, dyspareunia, complete or partial expulsion, prolonged menstrual flow, menstrual spotting, pain, cramping, and vaginitis were discussed in the labeling for ParaGard® Intrauterine Copper Contraceptive in August 2013 and thereafter and that prescribing physicians would be knowledgeable about information in the labeling. Defendant denies the remaining allegations in Paragraph 9 of plaintiff's Complaint.

10. Defendant admits only that risks of intrauterine pregnancy, ectopic pregnancy, pelvic infection, embedment, migration, perforation of the uterus, expulsion, Wilson disease, vaginal bleeding, septic abortion, dysmenorrhea, dyspareunia, complete or partial expulsion, prolonged menstrual flow, menstrual spotting, pain, cramping, and vaginitis were discussed in the labeling for ParaGard® Intrauterine Copper Contraceptive in August 2013 and thereafter. Defendant denies the allegations in Paragraph 10 of plaintiff's Complaint.

11. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of plaintiff's Complaint.

12. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of plaintiff's Complaint.

13. Defendant denies the allegations in Paragraph 13 of plaintiff's Complaint.

14. Defendant denies the allegations in Paragraph 14 of plaintiff's Complaint.

15. Defendant denies the allegations in Paragraph 15 of plaintiff's Complaint.

16. Defendant denies the allegations in Paragraph 16 of plaintiff's Complaint.

17. Defendant denies the allegations in Paragraph 17 of plaintiff's Complaint.

18. Defendant denies the allegations in Paragraph 18 of plaintiff's Complaint.

19. Defendant denies the allegations in Paragraph 19 of plaintiff's Complaint.

20. Defendant denies the allegations in Paragraph 20 of plaintiff's Complaint.

21. Defendant denies the allegations in Paragraph 21 of plaintiff's Complaint.

22. Defendant admits only that the ParaGard® Intrauterine Copper Contraceptive is placed in the uterus and that it is indicated for intrauterine contraception for up to ten years. Defendant denies the remaining allegations in Paragraph 22 of plaintiff's Complaint.

23. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 23 of plaintiff's Complaint.

24. Defendant denies the allegations in Paragraph 24 of plaintiff's Complaint.

25. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 of plaintiff's Complaint.

26. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26 of plaintiff's Complaint.

27. Paragraph 27 of plaintiff's Complaint alleges conclusions of law and allegations that are not directed to Defendant; therefore, no response is required. To the extent a response is required, Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 of plaintiff's Complaint.

28. Paragraph 28 of plaintiff's Complaint alleges conclusions of law and allegations that are not directed to Defendant; therefore, no response is required. To the extent a response is required, Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 of plaintiff's Complaint.

29. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of plaintiff's Complaint pertaining to plaintiff's alleged consultation with Dr. Amsbury. Defendant denies the remaining allegations in Paragraph 29 of plaintiff's Complaint.

30. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 of plaintiff's Complaint.

31. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 of plaintiff's Complaint.

COUNT I

32. Defendant denies each and every prior and subsequent allegation in plaintiff's Complaint except as expressly admitted above and below.

33. Paragraph 33 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 33 of plaintiff's Complaint.

34. Paragraph 34 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 34 of plaintiff's Complaint.

35. Defendant denies the allegations in Paragraph 35 of plaintiff's Complaint.

36. Defendant denies the allegations in Paragraph 36 of plaintiff's Complaint.

37. Defendant denies the allegations in Paragraph 37 of plaintiff's Complaint.

COUNT II

38. Defendant denies each and every prior and subsequent allegation in plaintiff's Complaint except as expressly admitted above and below.

39. Paragraph 39 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 39 of plaintiff's Complaint.

40. Paragraph 40 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 40 of plaintiff's Complaint.

41. Defendant denies the allegations in Paragraph 41 of plaintiff's Complaint.

42. Defendant denies the allegations in Paragraph 42 of plaintiff's Complaint.

43. Defendant denies the allegations in Paragraph 43 of plaintiff's Complaint.

COUNT III

44. Defendant denies each and every prior and subsequent allegation in plaintiff's Complaint except as expressly admitted above and below.

45. Paragraph 45 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 45 of plaintiff's Complaint.

46. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 46 of plaintiff's Complaint regarding plaintiff's alleged use of birth control or her state of mind. Paragraph 46 alleges conclusions of law to which no response is required. To the extent a response to those allegations is required, Defendant denies the allegations in Paragraph 46 of plaintiff's Complaint. Defendant denies the remaining allegations in Paragraph 46 of plaintiff's Complaint.

47. Defendant denies the allegations in Paragraph 47 of plaintiff's Complaint.

48. Defendant denies the allegations in Paragraph 48 of plaintiff's Complaint.

49. Defendant denies the allegations in Paragraph 49 of plaintiff's Complaint.

50. Defendant denies the allegations in Paragraph 50 of plaintiff's Complaint.

51. Defendant denies the allegations in Paragraph 51 of plaintiff's Complaint.

52. Defendant denies the allegations in Paragraph 52 of plaintiff's Complaint.

COUNT IV

53. Defendant denies each and every prior and subsequent allegation in plaintiff's Complaint except as expressly admitted above and below.

54. Defendant admits only that it has manufactured and sold and that Teva Pharmaceuticals USA, Inc. has sold ParaGard® Intrauterine Copper Contraceptives. Defendant denies the remaining allegations in Paragraph 54 of plaintiff's Complaint.

55. Defendant denies the allegations in Paragraph 55 of plaintiff's Complaint.

56. Defendant denies the allegations in Paragraph 56 of plaintiff's Complaint.

57. Paragraph 57 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 57 of plaintiff's Complaint.

58. Paragraph 58 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 58 of plaintiff's Complaint.

59. Paragraph 59 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 59 of plaintiff's Complaint.

COUNT V

60. Defendant denies each and every prior and subsequent allegation in plaintiff's Complaint except as expressly admitted above and below.

61. Paragraph 61 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 61 of plaintiff's Complaint.

62. Paragraph 62 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 62 of plaintiff's Complaint.

63. Paragraph 63 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 63 of plaintiff's Complaint.

64. Paragraph 64 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 64 of plaintiff's Complaint.

65. Paragraph 65 alleges conclusions of law to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 65 of plaintiff's Complaint.

COUNT VI

66. Defendant denies each and every prior and subsequent allegation in plaintiff's Complaint except as expressly admitted above and below.

67. Defendant denies the allegations in Paragraph 67 of plaintiff's Complaint.

68. Defendant denies the allegations in Paragraph 68 of plaintiff's Complaint.

69. Defendant denies the allegations in Paragraph 69 of plaintiff's Complaint.

70. Defendant denies the allegations in Paragraph 70 of plaintiff's Complaint.

71. Defendant denies the allegations in Paragraph 71 of plaintiff's Complaint.

COUNT VII

72. Defendant denies each and every prior and subsequent allegation in plaintiff's Complaint except as expressly admitted above and below.

73. Paragraph 73 of plaintiff's Complaint is not directed to Defendant; therefore, no response is required. To the extent a response is required, Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 73, including subparts (a) through (c), of plaintiff's Complaint.

74. Paragraph 74 of plaintiff's Complaint is not directed to Defendant; therefore, no response is required. To the extent a response is required, Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 74, including subparts (a) through (c), of plaintiff's Complaint.

75. Defendant admits only that plaintiff alleges damages in excess of the court's jurisdictional limit. Defendant denies the remaining allegations in Paragraph 75 of plaintiff's Complaint and denies that Defendant is liable to plaintiff.

DEFENSES

1. The Complaint fails in whole or in part to state a claim upon which relief can be granted. Defendant reserves the right to move before or at the time of trial to dismiss the Complaint.

2. The Complaint is barred because the Court lacks personal jurisdiction over Defendant.

3. Service is insufficient.
4. Service of process is insufficient.
5. Plaintiff's claims should be dismissed or transferred due to improper and/or inconvenient venue.
6. Plaintiff has failed to join all necessary and appropriate parties.
7. Defendant is not a proper party-defendant.
8. Any claim or cause of action that plaintiff may have had is barred by the applicable statutes of limitation and/or statutes of repose.
9. Plaintiff lacks standing to assert the claims alleged in the Complaint.
10. Plaintiff lacks capacity to assert the claims alleged in the Complaint.
11. Plaintiff's causes of action are barred by the doctrine of primary jurisdiction.
12. Plaintiff's claims are barred by the doctrine of unclean hands, laches, waiver and/or estoppel.
13. Plaintiff has failed to plead her claims with sufficient particularity.
14. Plaintiff is barred from recovering any damages because any alleged harm was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability.
15. The product at issue in plaintiff's Complaint was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused or contributed to cause plaintiff's alleged damages.
16. Any communications and/or actions between any of the defendants and the United States Food and Drug Administration and/or any governmental agency or entity are

constitutionally protected under the Noerr-Pennington Doctrine and the First Amendment to the United States Constitution.

17. Plaintiff's alleged damages, if any, were caused, in whole or in part, by plaintiff's own negligence and fault, and were not caused or contributed to in any manner by any fault, negligence, or breach of warranty of defendants.

18. Plaintiff's physicians and other medical care providers and their agents, servants, and employees were sophisticated users and learned intermediaries who had a duty to warn plaintiff of any alleged potential complications that might result from the product alleged to be at issue in this litigation. Plaintiff's physicians and other medical care providers possessed adequate information concerning warnings, precautions, and potential complications for those physicians and other medical care providers to assess the risks versus benefits of the product alleged to be at issue in this litigation. Therefore, plaintiff's claims are barred.

19. Plaintiff's alleged damages, if any, were caused solely by or contributed to by the act and fault of third parties for whom this defendant is not liable or responsible, and were not caused or contributed to by any act or fault of this defendant.

20. There is no responsibility for either the acts or omissions of the knowledgeable users or misinformation or lack of information provided to plaintiff by others.

21. ParaGard® Intrauterine Copper Contraceptives at all times conformed to the state of the art and the trade and custom in the industry as they existed at the time.

22. The benefits and utility of ParaGard® Intrauterine Copper Contraceptives outweigh the risk of danger or harm, if any, inherent in the product.

23. The damages claimed by plaintiff are too remote, speculative, and/or contingent to be legally compensable.

24. The injuries and damages claimed by plaintiff were caused, in whole or in part, by the acts or omissions of persons other than Defendant, over whom Defendant had no control. Therefore, any recovery by plaintiff should be apportioned in accordance with applicable law.

25. Plaintiff's damages, if any, were proximately caused by unforeseeable, independent, intervening, or superseding events beyond the control, and unrelated to the conduct of Defendant. The actions and omissions of Defendant, if any, were superseded by such unforeseeable, independent, intervening, and superseding events.

26. Plaintiff is at fault, and such fault was either the sole or at least a proximate cause of her claimed injuries and/or damages. Such fault should bar or reduce proportionally plaintiff's recovery, if any, in accordance with North Dakota or Florida law, and interpretative case law.

27. Any injuries or damages sustained by plaintiff were directly and proximately caused by the failure of plaintiff to heed warnings and instructions. Therefore, no recovery is available to plaintiff.

28. If plaintiff sustained damages as alleged in the Complaint, which is denied, plaintiff failed to mitigate her damages.

29. Misuse of the product, which was not reasonably foreseeable, caused plaintiff's alleged damages, if any, and plaintiff's claims therefore may be barred or reduced by applicable law.

30. Plaintiff's claims are barred to the extent the injuries alleged in the Complaint were caused or enhanced by pre-existing or unrelated medical, genetic, environmental, or psychiatric conditions, diseases or illnesses, by plaintiff's own idiosyncratic reactions, and/or by operation of nature.

31. Plaintiff's claims are barred on the grounds that plaintiff knew, or in the exercise of ordinary care should have known, of the risks of the injuries or damages alleged in the Complaint, if any, and nevertheless, did freely and voluntarily assume said risks, and in this undertaking proximately caused and contributed to the losses, injuries, or damage, if any, alleged by plaintiffs.

32. Plaintiff assumed all risks attendant with the use of the product at issue in plaintiff's Complaint in a manner other than directed.

33. Plaintiff's claims are barred by the learned-intermediary doctrine.

34. Plaintiff's claims are barred, in whole or in part, from recovery due to spoliation of evidence.

35. There were no warranties, either express or implied, between plaintiff and Defendant.

36. To the extent that the claims stated in the Complaint have been settled, compromised, or otherwise discharged, a set off is due.

37. Defendant adopts and relies upon all provisions and defenses afforded it under Restatement of Torts 2d, § 402A, including the comments thereto.

38. Defendant reserves the right to raise all defenses provided in sections 2, 4, and 6 of the Restatement (Third) of Torts: Product Liability, if the Court finds that it is applicable in this case.

39. The product at issue in the plaintiff's Complaint was not in an unreasonably dangerous condition.

40. Any fault on the part of this defendant, which is denied, was not the proximate cause of and did not contribute to any or all of plaintiff's alleged damages.

41. The product at issue in plaintiff's Complaint was not defective in manufacture, design, construction, or formulation and it conformed to all representations made by the manufacturer.

42. If plaintiff suffered or sustained any injuries, loss, or damage as a result of the alleged incident referred to in plaintiff's Complaint, the same were a direct result of plaintiff's failure to follow the reasonable advice of their healthcare providers.

43. The injuries or damages sustained by plaintiff, if any, may be attributed to several causes and accordingly should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

44. With respect to each and every cause of action, plaintiff is not entitled to recover because of the delay and the fundamental unfairness and prejudice due to the excessive delay from the date of the alleged use of the product and the filing the Complaint.

45. With respect to each and every purported cause of action, the acts of Defendant were, at all times, done in good faith and without malice.

46. Plaintiff failed to exercise ordinary care under the circumstances in using the product and such failure was the substantial cause of the occurrence that caused injury or damage, if any, to plaintiff.

47. Plaintiff's claims are preempted by federal law and regulation, particularly by the U.S. Food, Drug, and Cosmetic Act and the regulations promulgated pursuant to that act, and pursuant to the Supremacy Clause of the United States Constitution.

48. Plaintiff's breach of warranty claims are barred because plaintiff failed to give timely notice of any alleged breach of warranty, whether express or implied, to Defendant. Plaintiff also did not reasonably rely upon any alleged warranty, whether express or implied.

Plaintiff also failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty, whether express or implied and the warranty, whether express or implied, was adequately disclaimed, excluded, or modified.

49. Plaintiff's claims are barred for lack of privity.

50. Defendant had no duty to warn about any possible dangers that were not known at the time of manufacture and sale of the product in question.

51. Defendant hereby pleads all available defenses which may be available to it pursuant to the Chapter 28-01.3 of the North Dakota Century Code, and seeks the benefits of all product liability defenses which may be available to it pursuant to the laws of the State of North Dakota.

52. Defendant hereby pleads the available contribution defenses and principles as set forth in Chapter 32-38 of the North Dakota Century Code.

53. Liability for damages is limited by the provisions of Chapter 32-03.2 of the North Dakota Century Code.

54. Defendant hereby pleads all available defenses and principles as set forth in Fla. Stat. § 768.1257 regarding the state-of-the-art defense in products liability.

55. Defendant hereby pleads the available contribution defenses and principles as set forth in Fla. Stat. § 768.31.

56. Defendant hereby pleads the available comparative fault defenses and principles as set forth in Fla. Stat. § 768.81.

57. Defendant incorporates the defenses of all others who may become parties to this action as though fully set forth herein.

58. Plaintiff's claims are barred by additional defenses that may arise during the course of this litigation, which Defendant reserves the right to assert.

REQUEST FOR RELIEF

Teva Women's Health, Inc., respectfully requests that this Court:

1. Award to Teva Women's Health, Inc., its costs and attorneys' fees incurred in the defense of this action;
2. Dismiss plaintiff's Complaint with prejudice and without costs to Teva Women's Health, Inc.; and
3. Award to Teva Women's Health, Inc., such other relief as this Court deems just and equitable.

JURY DEMAND

Teva Women's Health, Inc., demands a trial by jury of the highest number the law allows.

Dated this 17th day of September, 2015.

Respectfully submitted,

PEARCE & DURICK

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*Attorney for Defendants Teva Pharmaceuticals
USA, Inc. and Teva Women's Health, Inc.*

CERTIFICATE OF SERVICE

I certify that on the 17th day of September, 2015, the foregoing document was filed with the Clerk of Court via email and that ECF will send a Notice of Electronic Filing (NEF) to the following:

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/s/ Zachary E. Pelham
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